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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/015,736	01/29/98	O'HAGAN	D 1397.002/230

HM12/0825

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EXAMINER

ZEMAN, M

ART UNIT

PAPER NUMBER

1643

8

DATE MAILED:

08/25/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/015,736

Applicant(s)

O'Hagan et al.

Examiner

Mary K Zeman

Group Art Unit

1643

☒ Responsive to communication(s) filed on the election filed 6/21/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) 6, 7, and 14-27 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5, 8-13, and 28-30 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. Applicant's election without traverse of Group I claims 1-13 and 28-30 in Paper No. 7 is acknowledged.
2. Claims 14-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 7.
3. The election of the E2 species of antigen is acknowledged. This election reads on claims 1-5, 8-13 and 28-30.

#### *Priority*

Priority under 35 U.S.C. 119(e) to provisional application 60/069,724, filed 12/16/97, is acknowledged.

#### *Specification*

4. The use of the trademark Span85, Tween80 and others has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Trademarks are not permitted in the claims.

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*Claim Rejections - 35 USC § 112*

5. Claims 4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 11 set forth trademarked names for chemical reagents. This is considered vague and indefinite, as the composition sold under a trademarked name may change over time, and then would not accurately describe the invention. Applicant is encouraged to replace the trademarked names with the chemical names of the reagents.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-3, 5, 9, 10 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Yeh et al. (US Patent 5,869,103).

The claims are drawn to vaccine compositions comprising a submicron oil in water emulsion and a microparticle comprising an antigen.

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Yeh (US Patent 5,869,103) discloses lactide and glycolide copolymer microparticles comprising various antigens, suspended in various adjuvants, including oil-in-water adjuvants. the antigen can be a viral antigen.

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-5, 8-13 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esparza in view of Higgins.

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The claims are drawn to vaccine compositions comprising lactide and glycolide microparticles and a submicron oil-in-water dispersion. Claim 4 sets forth the reagents of the adjuvant MF59. The antigen can be a viral antigen.

Esparza (Esparza et al. 1992 Vaccine Vol 10 No. 10 p 714-720) discloses PLA:PGA copolymer microparticles comprising an antigen, in a water-in-oil suspension, and tests the immunogenicity against the same microparticles suspended in an aqueous solution. Esparza concludes that both the microparticles and the emulsion have adjuvant activity, and that the vaccine comprising both the microparticles and the emulsion induced the strongest secondary antibody responses. Esparza does not disclose an oil-in-water emulsion.

Higgins (Vaccine 1996 Vol 14 No 6 pages 478-484; AG-1 PTO-1449) discloses the submicron oil-in-water adjuvant MF59, and its adjuvant properties in viral vaccines. Higgins states that MF59 has been shown to increase antibody responses to a variety of viral vaccines, including HIV and HCV vaccines. Higgins discloses that MF59 can significantly increase antibody response in vaccination.

Taken together, the instant invention appears to be the same or slightly different from the prior art of evaluating the efficacy of various adjuvants, alone or in combination, for optimization of a vaccine formulation.

One of ordinary skill in the art at the time the invention was made would have been motivated to select and evaluate the efficacy of differing adjuvants added to vaccines in order to increase immune system response to those antigens. Esparza shows that combining the

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microparticles with an emulsion provides increased immune response, and Higgins discloses the same emulsion being claimed, and demonstrates its effectiveness in viral vaccination. One would have looked to Higgins, as all of the reagents in the formulation are safe and approved for use in humans, and the emulsion provides significant improvements over the art. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

*Conclusion*

10. No claim is allowed.

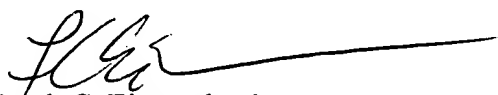
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Eisenschenk, can be reached on (703) 308-0452.

The fax number for this Art Unit is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz  
August 12, 1999

  
Frank C. Eisenschenk  
Supervisory Patent Examiner, Group 1600